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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,643	12/01/2000	Steven M. Ruben	PZ040P1	2092

22195 7590 10/29/2003

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EXAMINER	
SPIEGLER, ALEXANDER H	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/726,643	RUBEN ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. This Office action is in response to Applicants' response of August 27, 2003. Currently, claims 24-75 are pending and are rejected.

All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 24-75 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, due to its not being supported by a substantial asserted utility or a well-established utility.

To satisfy the utility requirement, the claimed invention must have a specific and substantial utility, or in the alternative, the claimed invention must have a well-established utility. In the instant case, the claimed invention does not have a substantial utility or a well-established utility. Applicants' assertion that SEQ ID NO: 56 may be used as a marker for B-cell lymphoma is considered as a specific utility.

I. *The specification does not assert a substantial utility because the utilities asserted by Applicants requires or constitutes carrying out further research to identify or reasonably confirm a "real world" use.*

MPEP 2107.01 states:

A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities...the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;

The specification states Gene 11 (i.e., HYACJ27cDNA), which encodes SEQ ID NO: 56 is expressed "primarily" in B-cell lymphoma (see page 36). However, no protein expression data of SEQ ID NO: 56 is provided. That is, the specification is silent as to any expression patterns of SEQ ID NO: 56. For example, the specification does not show that SEQ ID NO: 56 is expressed in individuals with B-cell lymphoma, but not in normal individuals, or SEQ ID NO: 56 is over expressed in individuals with B-cell lymphoma, as compared to normal individuals.

The specification postulates that expression of the protein of SEQ ID NO: 56 may be useful in treatment and diagnoses of cancers and disorders of the immune and hemopoietic systems, including but not limited to anemia, pancytopenia, leukopenia, thrombocytopenia or leukemia (pg. 36). The specification further suggests that the protein of SEQ ID NO: 56 could be used in the treatment of immunological disorders, such as infection, inflammation, allergy, immunodeficiency, etc. (pg. 36). Finally, the specification asserts that SEQ ID NO: 56 can be used as a marker for B-cell lymphoma (pg. 37).

In order for a polypeptide to be useful for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polypeptide and a disease or disorder. The presence of a polypeptide in tissue that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information

regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polypeptide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polypeptide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e., overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polypeptide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed protein and any disease or disorder and the lack of any correlation between the claimed polypeptide with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ 692 (US SupCt 1966).

Additionally, in Brenner v. Manson, 148 USPQ 696 (US SupCt 1966) the Court stated, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy."

In the instant case, the specification has only taught that Gene 11 is "expressed primarily in B-cell Lymphoma". However, the specification does not teach any information regarding the protein expression of SEQ ID NO: 56, nor does it teach whether normal individuals expressed Gene 11, or what this expression was compared to, as to conclude that the gene is "expressed

primarily". Therefore, the specification, at best, provides only a starting point for using SEQ ID NO: 56. It is apparent that extensive further research, not considered to be routine experimentation, would be required before one skilled in the art would know how to use the claimed invention. One skilled in the art would need to carry out further research to find a substantial utility for the invention as claimed, and therefore, the invention as claimed, is merely considered to be a research tool. Accordingly, the alleged utilities summarized above do not define a "real world" use because the claimed polypeptide can only be used for "basic research such as studying the properties of the claimed product itself *or the mechanisms in which the material is involved*" (e.g., using SEQ ID NO: 56 as a marker for B-cell lymphoma) (emphasis added).

II. *The specification is not supported by a well-established utility because one of ordinary skill in the art would not immediately appreciate why the invention is useful based on the characteristics on the invention.*

MPEP 2107 states:

> "An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible."

Applicants have provided little to no evidence of the characteristics of the specifically claimed polypeptide, the specification is not substantial, and based on the laundry lists of possible asserted utilities, it is not apparent as to how "a person of ordinary skill in the art would immediately appreciate why the invention is useful". This is evidenced by the fact that further research would need to be carried out by the skilled artisan even given SEQ ID NO: 56. For example, given SEQ ID NO: 56, a skilled artisan would have to carry out experiments to

determine whether SEQ ID NO: 56 is expressed in diseased individuals and not in normal individuals, or whether SEQ ID NO: 56 is overexpressed in diseased individuals, as compared to normal individuals, etc. Furthermore, Applicants assert that their invention "relates to newly identified...polypeptides...uses of polynucleotides, polypeptides", which suggests there is no "well-established" utility for SEQ ID NO: 56. For these reasons, the specification is not supported by a well-established utility.

Accordingly, the claimed invention is not supported by a substantial asserted utility or a well-established utility.

4. Claims 24-75 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by a substantial or well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicants Arguments

Applicants' argue the specification's teaching that the gene encoding SEQ ID NO: 56 is expressed "primarily" in B-cell lymphoma satisfies the substantial prong of the 35 U.S.C. 101 analysis. Furthermore, Applicants' argue Dr. George Komatsoulis's declaration substantiates the assertion that the expression of the polynucleotide encoding SEQ ID NO: 56 was preferentially observed in B cell lymphoma cells as opposed to normal non-leukemic B cells. Applicants also argue the instant invention has a well-established utility because it is not a "throw away" utility.

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for several reasons. First, while the specification teaches the gene encoding SEQ ID NO: 56 is "primarily" expressed

in B-cell lymphoma, the specification does not teach whether this expression was found in other samples or what other samples were being compared (e.g., normal B cells, etc.). Thus, it is not clear as to what the expression pattern is being compared to, which would allow for one to conclude that the gene is "primarily" expressed in B cell lymphoma. There is no reference as to other tissues or samples tested, and therefore, the skilled artisan would necessarily need to carry out further research to find a substantial utility for the invention as claimed.

Applicants' submit the declaration of Dr. George Komatsoulis in support of the position that "the expression of the polynucleotide of SEQ ID NO: 56 was assessed in B cell lymphoma, as well as many other normal, non-leukemic cells and hematopoietic cells". (see Applicants' response on page 13).

It is noted that Dr. Komatsoulis is not an inventor of the instant application. In short, the declaration states, "I *have personal knowledge* that the expression of the polynucleotide of SEQ ID NO: 56 *was assessed* in several hundreds of libraries representing immune and non-immune human tissues...". (emphasis added)

The declarant's comments are acknowledged. However, the declaration is found insufficient in the absence of objective evidence to support declarant's assertions. It is suggested that Applicants resubmit a declaration which details objective evidence to support Applicants' assertion that expression of the polynucleotide of SEQ ID NO: 56 was only observed in B cell lymphoma cells, as opposed to non-leukemic B cells and hematopoietic cells. This rejection will be withdrawn by a showing of this objective evidence.

Applicants' argument regarding an alleged well-established utility has also been considered, but is not persuasive because the claims do not have a substantial utility, and therefore, the claims do not have a well-established utility.

Conclusion

5. No claims are allowable.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

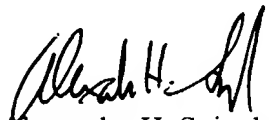
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alexander H. Spiegler
October 24, 2003

CARLA J. MYERS
PRIMARY EXAMINER